

To: 5.1.2e [5.1.2e] <[5.1.2e]@ec.europa.eu>
 Cc: 5.1.2e [5.1.2e] [JPPBE] <[5.1.2e]@ITS.JNJ.com>; 5.1.2e [5.1.2e] <[5.1.2e]@ec.europa.eu>; 5.1.2e [JRDNL] <[5.1.2e]@its.jnj.com>
 From: 5.1.2e [JPPBE]
 Sent: Tue 4/27/2021 10:10:08 AM
 Subject: additional clarification : Covid 19 export authorisation request
 Received: Tue 4/27/2021 10:10:08 AM

Dear 5.1.2e

There are indeed four pending export authorisations to the UK (2 submitted on 19th of April, 2 submitted on 22nd of April), all are extremely critical for our clinical COVID-19 vaccine related work.

We need to get the permit for these clinical samples **at the very latest end of this week**, otherwise this will delay the start-up of our **first in human clinical trials of our COVID-19 Vaccine against variants**.

We have another permit prepared (not submitted) that relates to 5.1.2f. These samples are needed for similar analytical safety tests 5.1.2f. Given the apparent sensitivity of the first set of requests, we wanted to give you a heads up prior to even sending it to the Dutch authorities. This request will be sent tomorrow. Any delay of this validation would impact our ability to produce drug substance in the Netherlands. Also this export permit will be required as soon as possible.

The reason we send this to 5.1.2f is that this Lab is one of the few labs in the world with experience in these type of testing.

Also, as indicated before, the number of doses that these shipments represent is totally artificial, no single dose can be made out of it and the materials used for testing are destroyed afterwards

As per our ODP discussions with 5.1.2e we would like to come back to our request to set up a **monthly meeting where we can explain other upcoming shipments** prior to submitting these for formal approval. Especially since there are some similar shipments scheduled in the next weeks and we would like to avoid potential confusion.

Happy to discuss over the phone if needed
 Kind regards

5.1.2e on behalf of the Janssen COVID-19 Vaccine team

From: 5.1.2e <[5.1.2e]@ec.europa.eu>
 Sent: vrijdag 23 april 2021 7:36
 To: 5.1.2e [JRDNL] <[5.1.2e]@its.jnj.com>
 Cc: 5.1.2e [JPPBE] <[5.1.2e]@ITS.JNJ.com>; 5.1.2e [JPPBE] <[5.1.2e]@ITS.JNJ.com>; 5.1.2e <[5.1.2e]@ec.europa.eu>; 5.1.2e <[5.1.2e]@ec.europa.eu>
 Subject: [EXTERNAL] RE: heads up volumes FW: Covid 19 export authorisation request

Dearest 5.1.2e
 This is just one of the requests.
 Best wishes,

5.1.2e

From: 5.1.2e [JRDNL] <[5.1.2e]@its.jnj.com>
 Sent: Thursday, April 22, 2021 11:56 PM
 To: 5.1.2e (SANTE) <[5.1.2e]@ec.europa.eu>
 Cc: 5.1.2e [JRDNL] <[5.1.2e]@its.jnj.com>; 5.1.2e [JPPBE] <[5.1.2e]@ITS.JNJ.com>; 5.1.2e [JPPBE] <[5.1.2e]@ITS.JNJ.com>
 Subject: FW: heads up volumes FW: Covid 19 export authorisation request

Dear 5.1.2e

Find hereunder more information on the export authorization request we were discussing.

The **Attachment** contains the details of our request for authorisation of the export from Janssen Vaccines in Leiden to

5.1.2f		of 3 types of samples from one drug substance batch:	
5.1.1c	5.1.1c	5.1.1c	
5.1.1c	5.1.1c	5.1.1c	5.1.2f
5.1.1c	5.1.1c	5.1.1c	

All for destructive release testing and planned to ship on next week after receipt of this license. To the extent a theoretical equivalent yield is a condition for your approval, the total theoretical equivalent yield could potentially result in 5.1.1c vaccine doses.

These samples are needed for release testing at an external lab 5.1.2f These samples are not intended to be used for actual vaccination.

The export does not pose a threat to the execution of the APA between Janssen Pharmaceutica NV and the Union. It furthermore does not pose a threat to the security of supply within the Union, considering the principles of reciprocity and proportionality. We respectfully submit that granting the request for export authorisation would ensure compliance with Article 5(1) of Regulation 2015/479 since export controls on samples for testing purposes cannot be justified in order to prevent a critical situation from arising an account of a shortage of essential products, or to remedy such a situation.

Please do not hesitate to contact us immediately should you have any further comments or questions.

Best regards, 5.1.2e

5.1.2e



Janssen Vaccines and Prevention B.V.
Archimedesweg 4-6, 2333 CN Leiden, The Netherlands

PO Box 2048, 2301 CA Leiden, The Netherlands

Mobile: 5.1.2e

Phone office: 5.1.2e

5.1.2e @its.jnj.com

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